Remarks

Claims 1, 5-9, 11-19, 27 and 29-88 will be pending in the instant application on entry of the present amendment. Claims 10 and 20-23, which have been withdrawn from consideration by the Examiner as being directed to nonelected subject matter, have been cancelled without prejudice or disclaimer. Applicants reserve the right to pursue claims to the cancelled subject matter in one or more divisional applications.

Claim 1(d) has been amended to recite "TR16-long polypeptide having the amino acid sequence encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 1(e) has been amended to recite "TR16-short polypeptide having the amino acid sequence encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Claim 1(h) has been amended to recite "the TR16 intracellular domain comprising amino acids from about 949 to about 1027 in SEQ ID NO:4." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraph [0025]. Claim 1 has been amended so as to add a new part (i), which recites "a nucleotide sequence encoding the TR16 intracellular domain comprising amino acids from about 949 to about 963 in SEQ ID NO:2." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraph [0022]. Claim 1(i) has been relabeled as (j) and amended so as to recite "the TR16-long receptor." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 1 has been amended so as to add a new part (k), which recites "a nucleotide sequence encoding the TR16-short receptor

extracellular and intracellular domains with all or part of the transmembrane domain deleted." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Subsequently, parts (j), (k), (l), (m) and (n) of claim 1 have been relabeled as parts (l), (m), (n), (o) and (p) respectively. Newly labeled claim 1(p) has been altered so as to recite "(m), (n), (o) or (p)." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014], [0022] and [0025]. Claim 8 has been amended so as to recite "(m), (n), (o) or (p)." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014], [0022] and [0025]. Claim 9 has been amended so as to recite "comprising at least 10 amino acid residues." Support for this amendment may be found in the original claims and in the specification as originally filed, for example, at paragraph [0138]. Claim 9 has been amended so as to recite "(l), (m), (n), or (o)." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014], [0022] and [0025]. Claim 13 has been amended so as to recite "the TR16-long intracellular domain." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 19(a) has been amended so as to recite "the nucleotide sequence contained in ATCC Deposit No. PTA-506 encoding the TR16-long polypeptide." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 19(b) has been amended so as to recite "the nucleotide sequence contained in ATCC Deposit No. PTA-506 encoding the TR16-short polypeptide." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Claim 27(d) has been

amended to recite "TR16-long polypeptide having the amino acid sequence encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 27(e) has been amended to recite "TR16-short polypeptide having the amino acid sequence encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Claim 27(h) has been amended to recite "the TR16 intracellular domain comprising amino acids from about 949 to about 1027 in SEQ ID NO:4." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraph [0025]. Claim 27 has been amended so as to add a new part (i), which recites "a nucleotide sequence encoding the TR16 intracellular domain comprising amino acids from about 949 to about 963 in SEQ ID NO:2." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraph [0022]. Claim 27(i) has been relabeled as (j) and amended so as to recite "the TR16-long receptor." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claim 27 has been amended so as to add a new part (k), which recites "a nucleotide sequence encoding the TR16-short receptor extracellular and intracellular domains with all or part of the transmembrane domain deleted." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Subsequently, parts (j), (k), (l), (m) and (n) of claim 27 have been relabeled as parts (l), (m), (n), (o) and (p) respectively. Newly labeled claim 27(p) has been altered so as to recite "(l), (m), (n), or (o)." Support for this amendment may be found in the original claims and in the

specification as filed, for example, at paragraphs [0014], [0022] and [0025]. Claims 62(a), (b) and (c) have been amended so as to recite "TR16-long polypeptide encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claims 62(d), (e) and (f) have been amended so as to recite "TR16-short polypeptide encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Claims 88(a), (b) and (c) have been amended so as to recite "TR16-long polypeptide encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0025]. Claims 88(d), (e) and (f) have been amended so as to recite "TR16-short polypeptide encoded by a cDNA contained in ATCC Deposit No. PTA-506." Support for this amendment may be found in the original claims and in the specification as filed, for example, at paragraphs [0014] and [0022]. Accordingly, no new matter has been added by amendment.

The specification has been amended to address the informalities identified and objected to by the Examiner. *See*, Paper No. 13, pages 6-7. The title of the invention has been amended as suggested by the Examiner in Paper. No. 13. The priority statement in the first paragraph of the specification has been amended to recite "now abandoned" as suggested by the Examiner in Paper No. 13. Paragraphs [0023], [0029] and [0030] have each been amended to recite "Figure 2A-D" as suggested by the Examiner in Paper No. 13. Paragraph [0025] has been amended so as to identify sequences in Figure 4 using the required sequence identifier (SEQ ID NO:) as suggested by the Examiner in Paper No. 13, support for this amendment may be found in the specification as originally filed at

paragraphs [0034] and [0043]. Support for these amendments to the specification may be found throughout the specification and drawings as originally filed. Accordingly, no new matter has been added by amendment.

I. Double patenting

The Examiner has provisionally rejected claims 1, 5-9, 11-19, 27 and 29-88, under 35 U.S.C. § 101, as allegedly "claiming the same invention as that of claims 1-19 and 26 of copending Application No. 10/140,164." *See*, Paper No.13, page 8.

As claims have not been found allowable in either the instant application or Application No. 10/140,164, Applicants respectfully request that the present rejection be held in abeyance until such time as claims are deemed to be in condition for allowance in either one of the two above-mentioned applications.

II. Rejections under 35 U.S.C. §§ 101 and 112

A. 35 U.S.C. § 101

The Examiner has rejected claims 1, 5-9, 11-19, 27 and 29-88, under 35 U.S.C. § 101, as allegedly "not supported by either a specific and substantial asserted utility or a well-established utility." *See*, Paper No.13, pages 8-13. Applicants respectfully disagree and traverse the rejection.

In particular, the Examiner lists certain of the asserted activities and utilities of TR16 and alleges these are "general activities that would apply to virtually any protein in the tumor necrosis receptor family, and are not specific to this particular protein." *See*, Paper No. 13, Page 9.

Applicants respectfully disagree and traverse this rejection. Contrary to the Examiner's comments, Applicants have set forth in the specification statements that clearly and fully describe the function of TR16 of the present invention and explain why Applicants believe the invention is useful. Applicants contend that specific and substantial utilities have been disclosed in the specification as filed and that the only issue is whether any asserted utility is credible. For example, the specification, at paragraphs [0188] to [0191], teaches that TR16 is expressed in B cells and spleen, and that polynucleotides of the invention are useful in the diagnosis of tumors including B cell and monocytic cell leukemias and lymphomas, and immune system-related disorders. Applicants assert that such characterization is sufficient on its own to constitute a showing of utility.

A rejection under 35 U.S.C. § 101 is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. *See*, M.P.E.P. §§ 2107.02(II), (III) at 2100-[37-39] (Original Eighth Edition, Aug. 2001). In addition, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."). *See*, M.P.E.P. at 2100-37. Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. *See*, M.P.E.P. § 2107.02(II)(B) at 2100-[38-39].

Moreover, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. *See*, M.P.E.P. § 2107.01(III)(A) at 2100-[39-40]. Thus, the Examiner must

provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*; *see also*, *In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

Moreover, Applicants respectfully submit that polynucleotides of the invention that encode a TR16 polypeptide (such as, for example, the polynucleotide shown as SEQ ID NO:1), have an immediate and specific utility. As described above, such polynucleotides may be used to diagnose tumors including B cell leukemias and lymphomas and/or immune system-related disorders. Such polynucleotides of the invention encode and may therefore be used to produce TR16 polypeptides. *See*, *e.g.*., specification, at paragraph [0014]. Such polypeptides may then be used to generate antibodies specific for TR16. *See*, *e.g.*, specification, at paragraph [0049]. The specification as originally filed teaches that "TR16 is expressed in B cells and spleen." *See*, specification, at paragraph [0189]. The specification as originally filed also teaches that:

> polynucleotides of the invention (e.g., polynucleotide sequences complementary to all or a portion of TR16-short and/or TR16-long mRNA) and antibodies (and antibody fragments) directed against the polypeptides of the invention may be used to quantitate or qualitate concentrations of cells of B cell lineage (e.g., B cell leukemia cells) expressing TR16-short and/or TR16-long on their cell surfaces.

See, specification, at paragraph [0190]. Thus, polynucleotides of the invention are supported by an immediate utility that is both specific and substantial.

Applicants submit that these asserted utilities for TR16 are specific (not every protein is expressed by cells of the immune system and can be used to measure abnormalities in that system) and substantial ("the general rule [is] that the treatments of specific diseases or conditions meet the criteria of 35 U.S.C. § 101." *See*, M.P.E.P. § 2107.01(III) at 2100-[34-35]. In addition, Applicants submit that these utilities are credible. The Examiner has failed, however, to provide any countervailing statements as to why these particular utilities are not specific, substantial and credible.

Even assuming, *arguendo,* the Examiner has established a *prima facie* showing that the claimed invention lacks utility, Applicants respectfully submit that they have rebutted the Examiner's showing by proffering sufficient evidence to lead one skilled in the art to conclude that the asserted utilities are more likely than not true. Applicants have directed the Examiner to the specification where clear and specific assertions are made of TR16 diagnostic utility.

In view of the above, Applicants submit that the asserted utilities of the invention meet the statutory requirement set forth in 35 U.S.C. § 101. The Examiner has failed to establish and maintain grounds as to why a rejection for lack of utility is proper. Accordingly, Applicants respectfully request that the rejection be withdrawn.

B. 35 U.S.C. § 112, first paragraph

1. Enablement

a. The Examiner has rejected claims 1, 5-9, 11-19, 27 and 29-88, under 35 U.S.C. § 112, first paragraph, allegedly "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons

set forth above, one skilled in the art clearly would not know how to use the claimed invention." *See*, Paper No. 13, page 13.

As described in detail above, Applicants submit that the asserted utilities of the invention meet the statutory requirement set forth in 35 U.S.C. § 101 and that armed with the specification of the instant invention, one skilled in the art clearly would know how to use the claimed invention. Accordingly, Applicants respectfully request that the rejection be withdrawn.

b. The Examiner has rejected claims 1, 5-9, 11-19, 27 and 62-88, under 35 U.S.C. § 112, first paragraph, as allegedly containing "subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." *See*, Paper No. 13, page 14.

More specifically the Examiner asserts that "Applicants referral to the deposit of cDNA clones HTWBD48 and HLICS62 on page 5 of the specification is an insufficient assurance that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met." Applicants respectfully direct the Examiner's attention to the enclosed Statement Concerning the Deposited cDNA Clones.

In view of the enclosed Statement regarding availability of the deposited clones, Applicants believe the Examiner's concerns have been fully addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 5-9, 11-19, 27 and 62-88, under 35 U.S.C. § 112, first paragraph, for lack of enablement.

2. Written Description

The Examiner has rejected claims 1, 8, 9, 11-19, 27, 29, 30, 33, 36, 39, 42, 45, 48-60, 62, 63, 65, 67, 69, 71, 73 and 75-87, under 35 U.S.C. § 112, first paragraph, as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *See*, Paper No. 13, page 15.

The Examiner further alleges that "the claims as written include nucleic acid molecules encoding polypeptides comprising fragments and homologues, encompass polypeptides that vary substantially in length and also in amino acid composition." *See*, Paper No. 13, page 15, lines 8-11. The rejection is respectfully traversed. Applicants assert that each of the claims pending prior to and after the present amendment is fully supported and satisfies the statutory written description requirements under 35 U.S.C. § 112.

In an analysis of written description under 35 U.S.C. § 112, first paragraph, the Examiner bears the initial burden of presenting a *prima facie* case of unpatentability. This burden is only discharged if the Examiner can present evidence or reasons why one skilled in the art would not reasonably conclude that Applicants possessed the subject matter as of the priority date of the present application. *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q.2d 90, 96 (C.C.P.A. 1976); M.P.E.P. § 2163.04. In the instant case, Applicants maintain that the Examiner has not met this burden.

Claims 1, 8, 9, 11-19, 27, 29, 30, 33, 36, 39, 42, 45, 48-60, 62, 63, 65, 67, 69, 71, 73 and 75-87, stand rejected because "[t]here is no functional limitation in the claims, and some of the claims require only a very small amount of structure ... [t]he instantly claimed

genus is not so limited and the prior art does not provide compensatory structural or correlative teachings to enable one of skill to identify the polynucleotides encompassed." *See*, Paper No. 13, page 17, lines 8-15. The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor had possession of the claimed invention based on the specification as filed. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); M.P.E.P. § 2163.02. Indeed, as the Federal Circuit has noted, "the issue is whether one of skill in the art could derive the claimed ranges from the patent's disclosure." *Union Oil Company of California v. Atlantic Richfield Company*, 208 F.3d 989, 54 U.S.P.Q. 2d 1227 (Fed. Cir. 2000) (emphasis added).

It is well established that a "gene is a chemical compound, albeit a complex one". *Amgen, Inc. v. Chugai Pharamceutical Co., LTD.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991). Thus, the claims of the instant application, directed to particular polynucleotides encoding polypeptides having the amino acid sequences of SEQ ID NO:2 or SEQ ID NO:4 or encoded by the cDNAs contained in ATCC Deposit No. PTA-506, are essentially chemical claims involving generic chemical formulae. As stated by Judge Lourie in *University of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997), "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass." All of the objectives met by a generic chemical formula are similarly met by the explicit description in the instant specification of a polynucleotide sequence (*i.e.*, SEQ ID NO:1 or SEQ ID NO:3), the amino acid sequence encoded thereby (*i.e.*, SEQ ID NO:2 or SEQ ID NO:4), and by the instant claims to polynucleotides at least 95% identical to polynucleotides encoding

polypeptides comprising amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4, and polynucleotides encoding polypeptides comprising amino acid sequences at least 95% identical to amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4. That is, the instant claims clearly distinguish the boundaries of the claimed genera and identify all of the members of those genera. Accordingly, one skilled in the art would reasonably conclude that Applicants had possession of the polynucleotides encompassed by the rejected claims upon reading the present application as filed, and would immediately recognize that the Applicants had "invented what is claimed" (*Vas-Cath*, 935 F.2d at 1563). Therefore, the specification contains an adequate written description of the claimed polynucleotides. Applicants have provided the skilled artisan with a "generic formula" in the form of the amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4, which indicates "with specificity what the generic claims encompass." Armed with this information "one skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass."

Furthermore, the specification particularly teaches on embodiments of the invention rejected by the Examiner in the present action. Accordingly, one skilled in the art, enlightened by the teachings of the present application, could readily envision all of the various polynucleotide sequences that comprise the specified polynucleotides. For example, the skilled artisan could easily substitute a nucleic acid codon encoding any given amino acid residue for a codon encoding any other given residue, or add or delete codons, such that nothing more than what is described in the specification would be required to identify every single one of the polynucleotides at least 95% identical to polynucleotides encoding polypeptides comprising amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4, or polynucleotides encoding polypeptides comprising amino acid

sequences that are at least 95% identical to the amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4. Thus, it would be readily apparent to the skilled artisan that the Applicants had "invented what is claimed" (*Vas-Cath*, 935 F.2d at 1563).

For all of the above reasons, Applicants respectfully assert that the Examiner has failed to meet the required burden in presenting evidence or reasons why those skilled in the art would not recognize the claimed invention from the disclosure. Moreover, the specification conveys with reasonable clarity that Applicants were in possession of the claimed invention. Therefore, Applicants submit that the pending claims fully meet the written description requirements of 35 U.S.C. § 112, first paragraph, and respectfully request that the Examiner's rejection of the claims under 35 U.S.C. § 112, first paragraph, be reconsidered and withdrawn.

The Examiner has further asserted that "[g]iven the unpredictability of homology comparisons, and the fact that the specification fails to provide objective evidence that the additional sequences are indeed species of the claimed genus it cannot be established that a representative number of species have been disclosed to support the genus claim." *See*, Paper No. 13, page 16, line 23 through page 17, line 3. However, the Examiner has not established that a representative number of species have not been disclosed in support of the genus claim, or provided any showing that one skilled in the art would not reasonably conclude that Applicants possessed the claimed subject matter as of the priority date of the present application. Applicants respectfully submit that the entire claimed genus of polynucleotides is described such that a skilled artisan would recognize that Applicants were in possession of the genus. Applicants have not only described the species having the sequences of SEQ ID NO:1 and SEQ ID NO:3, which encode the entire amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4 respectively, they have also provided a

description sufficient to allow the skilled artisan to readily envision the additions, deletions, and substitutions falling within the claims. The claims recite polynucleotides that encode polypeptide molecules which comprise portions of the amino acid sequences of SEQ ID NO:2 and SEQ ID NO:4 with some variants as directed by the specification. The claims therefore read on described polynucleotide sequences.

Accordingly, Applicants respectfully request that the rejection of claims 1, 8, 9, 11-19, 27, 29, 30, 33, 36, 39, 42, 45, 48-60, 62, 63, 65, 67, 69, 71, 73 and 75-87, under 35 U.S.C. § 112, first paragraph, for lack of adequate written description, be reconsidered and withdrawn.

C. 35 U.S.C. § 112, second paragraph

The Examiner has rejected claims 1, 5-9, 11-18 and 27 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite "because claims 1, 13, and 27 encompass a nucleic acid molecule encoding ***the*** TR16 intracellular domain, and the specification discloses two TR16 polypeptides that have different intracellular domains, so it is not clear which intracellular domain is being claimed. The other claims are rejected for depending from claim 1." *See*, Paper No.13, page 18.

Applicants respectfully disagree and traverse the rejection. Preliminarily, Applicants point out that claim 27 does not depend from claim 1. However, in the interest of expediting prosecution, Applicants have amended claim 1 to recite "comprising amino acids from about 949 to about 1027 in SEQ ID NO:4" thereby mooting the present rejection.

The Examiner has further rejected claim 27(e) under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because "it encompasses a nucleotide sequence

encoding ***the*** mature TR16 polypeptide having the amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. PTA-506, and PTA-506 contains two cDNA clones, HTWBD48 and HLICS62." *See*, Paper No.13, page 18.

Applicants respectfully disagree and traverse the rejection. However, in the interest of expediting prosecution, Applicants have amended claim 27(e) to recite "the mature TR16 polypeptide having the amino acid sequence encoded by the cDNA clone HLICS62 contained in ATCC Deposit No. PTA-506" thereby mooting the present rejection.

The Examiner has further rejected claim 27 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because "the 'at least one' language of the claims does not place an upper limit on the extent of the changes to be made." *See*, Paper No.13, page 18.

Applicants respectfully disagree and traverse the rejection. However, in the interest of expediting prosecution, Applicants have amended claim 27 to recite "wherein said polypeptide has a sequence at least 95% identical to a sequence selected from the group consisting of" thereby mooting the present rejection.

Accordingly, Applicants respectfully request that the present rejection of claims 1, 5-9, 11-18 and 27 under 35 U.S.C. § 112, second paragraph, be reconsidered and withdrawn.

III. Priority

The Examiner has denied the claim of the present application to the benefit of prior application 09/637,856 and prior Provisional applications 60/268,364, 60/148,348, 60/148,683, 60/148,758, 60/148,870, 60/149,181, 60/149,453, and 60/149,498 under

35 U.S.C. §§120 and 119(e) respectively. *See*, Paper No. 13, pages 18-19. Accordingly, the Examiner has awarded an effective priority date of February 13, 2002, to the present application allegedly "because the claimed invention is not supported by either a specific and substantial utility or a well established utility." *See*, Paper No. 13, page 19. Applicants respectfully disagree and traverse this determination.

Determination that an application is not supported by either a specific and substantial utility or a well established utility, analogous to a rejection under 35 U.S.C. § 101, is improper when a person of ordinary skill in the art would find credible disclosed features or characteristics of the invention, or statements made by the applicant in the written description of the invention. *See,* M.P.E.P. §§ 2107.02(II), (III) at 2100-[38-40] (Feb. 2003). In addition, an applicant need only make *one* credible assertion of utility for the claimed invention to satisfy 35 U.S.C. § 101. *See, e.g., Raytheon v. Roper,* 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 835 (1984) ("When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown."). *See*, M.P.E.P. at 2100-37. Finding a lack of utility is also improper if a person of ordinary skill in the art would know of a use for the claimed invention at the time the application was filed. *See*, M.P.E.P. § 2107.02(II)(B) at 2100-[38-39]. Moreover, the burden is on the Examiner to establish why it is more likely than not that one of ordinary skill in the art would doubt *(i.e.,* "question") the truth of the statement of utility. *See*, M.P.E.P. § 2107.02(III) at 2100-[39-40] (emphasis added). Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the applicants' assertion of utility. *See id.*;

see also, *In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a determination that none of the presently claimed priority applications are supported by either a specific and substantial utility or a well established utility for lack of utility under 35 U.S.C. § 101.

Contrary to the Examiner's comments, Applicants have set forth in the earliest provisional application to which the present application claims priority benefit, statements that describe the utility of TR16 of the present invention.

The earliest provisional application to which the present application claims priority benefit under 35 U.S.C. § 119(e) is Provisional application No. 60/148,348, filed August 12, 1999 (the '348 application). The '348 application teaches that TR16 is a novel member of the Tumor Necrosis Factor receptor family (*see e.g.*, '348 application at page 1, lines 5-7), and that TNF receptor family members are expressed by a variety of cells including lymphocytes, and that they are involved in the regulation of proliferation and/or death of these cells (*see e.g.*, '348 application at page 1, line 12 through page 3, line 18). The '348 application further teaches that TR16 polynucleotides of the invention may be useful in the diagnosis of a disease which results from altered expression of TR16 or a soluble form thereof, such as, for example, tumors or autoimmune disease (*see e.g.*, '348 application at page 35, lines 4-8). Applicants assert that these asserted utilities, having been credible at the time of filing, are sufficient to constitute a showing of utility as required under 35 U.S.C. § 101.

In light of the above comments, Applicants assert that the '348 application, as well as each subsequently filed parent application, does indeed meet the statutory requirements of 35 U.S.C. §§ 101 and 112. Therefore, each of these applications is rightfully available

for benefit of priority under 35 U.S.C. §§ 120 and 119(e) to the present application. Accordingly, the effective priority date of the present application should correctly be the filing date of U.S. Provisional Application No. 60/148,348, *i.e.*, August 12, 1999.

IV. Rejections under 35 U.S.C. § 102

a. The Examiner has rejected claims 8 and 9 under 35 U.S.C. § 102(b) as allegedly "being anticipated by Shimkets et al., WO 00/78802, December 28, 2000 (cited by Applicants)." *See*, Paper No. 13, pages 19-20.

Applicants respectfully traverse the rejection. As discussed above, the correct effective priority date of the present application is August 12, 1999. Therefore, the teachings of Shimkets et al., being published as a reference on December 28, 2000, do not qualify as prior art against the present application under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the present rejection of claims 8 and 9 under 35 U.S.C. § 102(b) as being anticipated by the teachings of Shimkets et al. be reconsidered and withdrawn.

b. The Examiner has further rejected claims 8 and 9 under 35 U.S.C. § 102(e) as allegedly "being anticipated by Shimkets et al., US Patent Application Publication No US 20030032095A1, filing date Nov. 2, 2001." *See*, Paper No. 13, pages 20-21.

Applicants respectfully traverse the rejection. As discussed above, the correct effective priority date of the present application is August 12, 1999. Therefore, the teachings of Shimkets et al., having an effective 102(e) publication date of November 2, 2001, do not qualify as prior art against the present application under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the present rejection of claims 8 and 9

under 35 U.S.C. § 102(e) as being anticipated by the teachings of Shimkets et al. be reconsidered and withdrawn.

c. The Examiner has further rejected claims 8 and 9 under 35 U.S.C. § 102(a) as allegedly "being anticipated by Tashiro et al., EMBL/GenBank/DDBJ databases, Accession No. AK055902, December 1, 2001." *See*, Paper No. 13, page 21.

Applicants respectfully traverse the rejection. As discussed above, the correct effective priority date of the present application is August 12, 1999. Therefore, the teachings of Tashiro et al., having an effective publication date of December 1, 2001, do not qualify as prior art against the present application under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the present rejection of claims 8 and 9 under 35 U.S.C. § 102(a) as being anticipated by the teachings of Tashiro et al. be reconsidered and withdrawn.

d. The Examiner has further rejected claims 8 and 9 under 35 U.S.C. § 102(b) as allegedly "being anticipated by Hedge et al., Database EST, Accession No. AW954806, June 1, 2000." *See*, Paper No. 13, pages 21-22.

Applicants respectfully traverse the rejection. As discussed above, the correct effective priority date of the present application is August 12, 1999. Therefore, the teachings of Hedge et al., having an effective publication date of June 1, 2000, do not qualify as prior art against the present application under 35 U.S.C. § 102. Accordingly, Applicants respectfully request that the present rejection of claims 8 and 9 under 35 U.S.C. § 102(b) as being anticipated by the teachings of Hedge et al. be reconsidered and withdrawn.

e. The Examiner has further rejected claims 8 and 9 under 35 U.S.C. § 102(b) as allegedly "being anticipated by Bevins et al., US Patent No. 5,641,497." *See*, Paper No. 13, pages 22.

Preliminarily, Applicants point out that while claim 8 is listed as being rejected over Bevins et al., no grounds for this rejection is set forth in Paper No. 13. It is Applicants' understanding that claim 8 has been incorrectly listed, and that the Examiner intended only to include claim 9 in this rejection.

Applicants respectfully traverse the present rejection as it applies to claim 9. Bevins et al. disclose a polypeptide having eight contiguous amino acids in common with a portion of SEQ ID NOS:2 and 4 of the instant invention. In the interest of facilitating prosecution Applicants have amended claim 9 so as to recite "comprising at least 10 amino acid residues" thereby obviating the present rejection.

Accordingly, Applicants respectfully request that the present rejection of claims 8 and 9 under 35 U.S.C. § 102(b) as being anticipated by the teachings of Bevins et al. be reconsidered and withdrawn.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application.

In view of the foregoing remarks, applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: November 14, 2003

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Enclosures
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